

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Elections/Restrictions

Applicant had previously amended the claims to confirm with the elected subject matter as indicated in Applicant's Response to Restriction Requirement, filed December 6, 2006. In the Response, Applicant elected SEQ ID NO:12 as a species of the larger genus.

Telephonic Interview

Applicant wished to thank the Examiner for her time in discussing the Office Action with Dr. Michael Yamauchi, counsel representing the Applicant, on December 8, 2008 and again on March 6, 2009. As a result of the interviews, Applicant has supplied evidence in the form of a Declaration by the inventor that the utility of using the detection of a differentially expressed gene expression product extends to the situation where the gene expression product is a protein.

Amendments to the Claims

Applicant has amended Claims 28 and 29, as indicated by the Examiner to clarify that which Applicant regards as the invention. Applicant notes that Claim 14 was canceled with Applicant's Request for Continued Examination, filed on June 27, 2008. No new matter has been added. Entry of the amendments is respectfully requested.

Claims 1-7, 11, 13, 15, 16, 18-21, 23-31 and 33-61 are currently pending in this application, with claims 15, 28-30 and 37 drawn to elected subject matter.

Claim Rejections Under 35 USC §112, Second Paragraph

The Examiner has rejected Claims 28 and 29 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant has amended Claims 28 and 29 as indicated by the Examiner during a telephonic interview with Applicant's counsel on December 8, 2008, thereby obviating the rejection. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims Rejections Under 35 USC §101

The Examiner has maintained the rejection to Claims 14, 15, 28-30 and 37 under 35 U.S.C. §101 because the claimed invention is not supported by either a substantial asserted utility or a well established utility. The Examiner reasons that, although the Specification provides abundant support for the use of differentially expressed nucleic acid molecules for use in diagnostic methods, for which there would be a substantial utility, the Specification does not disclose the in vivo presence of a protein encoded by the disclosed nucleic acids (specifically those encoded by SEQ ID NO:12).

Applicant attaches herewith the Declaration of Dr. Jörn Bullerdiek. Dr. Bullerdiek comments on the knowledge of one of ordinary skill in the art at the time the present application was filed. As Dr. Bullerdiek indicates, the relationship between mRNA and protein expression is a central tenet of molecular biology. DNA encodes RNA, and RNA is translated into protein. Specifically, mRNA levels correspond to expressed protein levels. As Dr. Bullerdiek indicates, differential gene expression can be monitored by determining the level of expression of any gene expression product. Although the instant application discloses differential gene expression as measured by differential mRNA levels (a fact supported by the attached Exhibits B and C), Dr. Bullerdiek declares that differential expression can also be measured by determining the expression level of another gene expression product, namely, protein, as determined by using, for example, antibodies.

It is the differential gene expression of certain genes that allows for the diagnostic compositions and methods of the present application. Determination of the differential expression, regardless of whether it is determined by measuring mRNA levels or protein levels, allows for diagnosis of, for example, thyroid tumors, which clearly represents a substantial and credible utility.

The Examiner further indicates that the detection of SEQ ID NO:12, for example, is the detection of a chromosomal translocation. This assertion, however, is not entirely correct. The diagnostic methods, and the utility for such methods, derives from the differential expression of, for example, a SEQ ID NO:12 expression product. It is the expression value that is used for the utility, not the specific structural feature. This point is made clear by the data disclosed in the Specification and provided herewith in attached Exhibits B and C, which show that the coding sequence of SEQ ID NO:12, for example, is dramatically overexpressed relative to normal tissue. These data indicate it is the expression value of the gene expression product, not a particular structural feature, that is important for diagnostic methods.

In light of these comments and the declaration of Dr. Bulkerdiek, Applicant respectfully requests reconsideration and withdrawal of the rejection.

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

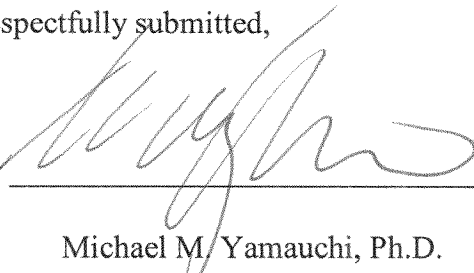
The Commissioner is hereby authorized to charge any additional fees that may be required regarding this application under 37 C.F.R. §§1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If an extension of time is needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extension fee to Deposit Account No. 19-0741.

Respectfully submitted,

Date

3/6/09

By



FOLEY & LARDNER LLP

Customer Number: 48329

Telephone: (617) 342-4088

Facsimile: (617) 342-4001

Michael M. Yamauchi, Ph.D.

Attorney for Applicant

Registration No. 58,468